IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	
FOSAMAX PRODUCTS LIABILITY LITIGATION	
***This Document Relates To*:**	
CARRIE SMITH, et al	
PLAINTIFFS,	**1:06-MD-1789 (JFK)**
-vs.-	**Cause No. 1:07-CV-09564-JFK**
MERCK & CO., INC. and MCKESSON CORPORATION	
DEFENDANT.	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO REMAND

Plaintiffs Carrie Smith, *et al.*, respectfully request that this Court remand this case back to the Superior Court of Los Angeles in California State Court because federal courts lack jurisdiction over the above mentioned lawsuit ("The Lawsuit").

Merck relied entirely on diversity for its removal from California State Court to Federal Court.[1] It argued that the non-diverse domestic Defendant, McKesson Corporation, an entity that Merck concedes has California as its principle place of business, is fraudulently joined. A party so moving bears the burden of proving that the plaintiff fraudulently joined the non-diverse defendant. Merck failed to meet its burden. In fact, under virtually identical circumstances,

[1] *See* Notice of Removal filed in state court, Exh. 1.

California US District Courts have rejected Merck's argument in this case. *See, e.g.*, *Martin v. Merck & Co., Inc.* 2005 WL 1984483, *3 (E.D.Cal.) (E.D.Cal.,2005), a Vioxx litigation case, considering the same arguments advanced by Merck and McKesson here (both were defendants there too). That court flatly rejected Merck's argument and remanded.

I.
STATEMENT OF FACTS

As set out in Plaintiff's Original Complaint in state court,[2] both Defendants were responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing and selling Fosamax.

Fosamax falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's Disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis. Fosamax is prescribed to increase bone mass.

In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant Merck as Fosamax.

Although the two defendant corporations appear to be maintained as separate corporate entities, they are operationally intertwined. Their strategy since the mid 90s has been market and sell Fosamax by misleading both prescribers and users about its risks. Merck outsourced its marketing response operations to McKesson. Robert Glaser, once a senior vice president for Merck U.S., a division of Merck & Co., Inc., had been responsible for launching some of Merck's "key brands, including Fosamax for osteoporosis." *See* Exhibit 3. Medsn Press release,

[2] *See* Exh. 2.

August 18, 2003 at 1. In 1998 Mr. Glaser went on to join McKesson, where he was charged with "marketing and patient services focused on improving the return on investment for pharmaceutical companies," including Merck. *Id.*

In November of 1998, McKesson announced formation of its DTC Solutions (SM) division with Mr. Glasser as its president. This division was created to provided data capture and management, advanced telecommunications support and a complete selection of printing, mailing and fulfillment services designed to optimize pharmaceutical manufacturers' investments in building one-to-one patient relationships. DTC says it was designed to provide:

> A comprehensive communications network and information management system to support direct-to-consumer (DTC) and direct-to-patient (DTP) marketing programs.

See Exhibit 4, McKesson Press Release, November 16, 1998 at 1. In the same press release, Mr. Glaser goes on to say "With DTC Solutions, McKesson assumes total responsibility for delivering an integrated, high quality program that manages all DTPC/DTP communications support activities …." *Id.*

The next month DTC acquired Kelly/Waldron, a sales force automation systems and services for pharmaceutical sales forces." *See* Exhibit 4, McKesson Press Release, December 21, 1998 at 1. As McKesson explained:

> Kelly/Waldron offers a broad array of decision support, marketing research …. Which enable pharmaceutical and biotechnology manufacturers to more cost effectively market their products to **physicians, nurses, physician assistants, other medical professionals** and consumers…. Kelly/Waldron is one of only ten licensees to the American Medical Association master database of all U.S. physicians.

Id. (bold emphasis added). McKesson marketed Fosamax both to consumers and to the prescribers. In the press release, Mr. Glaser goes on to say, "We will be in a position to provide compelling data to assist our manufacturing partners in developing and executing outcome

studies, Phase IV trials and other cost-effectiveness programs to improve manufacturer market share and clinical outcomes." *Id.*

McKesson clearly was not just a passive distributor. Merck and McKesson widely marketed Fosamax in the US both to consumers and to prescribers. The focus and goal of the promotional effort was to promote the perception by both consumers and prescribers that Fosamax was in fact safer than other treatments for bone density. Promotions further sought to minimize perception of potential risks.

As set out in the complaint, throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis and/or osteochemonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion and inflammation of the upper gastrointestinal tract, Merck and McKesson knew or should have known that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

Merck and McKesson also knew or should have known[3] that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Merck and McKesson knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

Merck and McKesson also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease

[3] The Plaintiffs explicitly pointed out in the complaint that whenever Plaintiffs assert Merck "should have known," Plaintiffs are asserting that the dangerous propensity of Fosamax was **knowable to one or both Defendants** given the accepted scientific knowledge at the time of manufacture and distribution.

can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on Fosamax.

Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

Shortly after Defendants began selling and distributing Fosamax, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates. Osteonecrosis and/or osteochemonecrosis of the jaw is a serious medical event and can result in severe disability and death.

After Fosamax was released, the FDA received a significant number of reports of osteonecrosis and/or osteochemonecrosis of the jaw among users of Fosamax. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review of bisphosphonates – specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel) and alendronate (Fosamax). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

As a result of the FDA Review, the FDA observed that the risk of osteonecrosis and/or osteochemonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis and/or osteochemonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, Fosamax.

As a result, the FDA recommended and stated that the labeling for Fosamax should be amended by Merck to specifically warn about the risk of osteonecrosis and/or

osteochemonecrosis of the jaw. Merck refused to accede to the FDA's request and, to this day, still does not properly warn of the risk of osteonecrosis and/or osteochemonecrosis of the jaw in its Fosamax labeling.

Rather than warn patients, and despite knowledge of an increased risk of osteonecrosis and/or osteochemonecrosis of the jaw on patients using Fosamax, Merck and McKesson continued to defend and promote Fosamax, mislead physicians and the public, and minimize unfavorable findings.

The Defendants knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but did not adequately and sufficiently warn consumers, including Plaintiffs, or the medical community, of such risks.

As a direct result of the marketing of Fosamax, Plaintiffs were prescribed Fosamax and have been permanently and severely injured, having suffered serious consequences from the ingestion of Fosamax. Plaintiffs require and will in the future require on-going medical care and treatment.

II.
ARGUMENT AND AUTHORITIES

A. Legal Standards for Diversity Jurisdiction and Fraudulent Joinder

Actions are removable under Title 28 U.S.C.A. § 1441(b) only if none of the parties properly joined and served as a defendant is a citizen of the State in which such action is brought. "The removal statute is strictly construed against removal and any doubt must be resolved in favor of remand." *Hofler v. Aetna US Healthcare of California*, 296 F.3d 764, 767 (9th Cir. 2002); *Gaus v. Miles Inc*., 980 F.2d 564, 566 (9th Cir.1992). The burden of proving all jurisdictional facts is on the party seeking removal. *Lew v. Moss*, 797 F.2d 747, 749 (9th Cir. 1986). Thus, Merck has the burden of establishing all elements of diversity jurisdiction. *See*

Pullman Co. v. Jenkins, 305 U.S. 534, 540, 59 S.Ct. 347 (1939); see also *Rockwell Int'l Credit Corp. v. U.S. Aircraft Ins. Grp.*, 823 F.2d 302, 304 (9th Cir. 1987).

Here, Merck alleges fraudulent joinder. "There is a presumption against finding fraudulent joinder, and defendants who assert that a plaintiff has fraudulently joined a party carry a heavy burden of persuasion." *Hart v. Bayer Corp.*, 199 F.3d 239, 246 (5th Cir. 2000). *Plute v. Roadway Package Sys., Inc.*, 141 F. Supp.2d 1005, 1008 (N.D. Cal. 2001). The moving party carries it only by proving: (1) that there is no possibility that plaintiff would be able to establish a cause of action in state court or (2) outright fraud in the pleading of jurisdictional facts. *Hart*, 199 F.3d at 247. Claims of fraudulent joinder must be denied where, as here, there is any possibility that the plaintiff may prevail on the cause of action against the in-state defendant. *See Id.* at 1008, 1012.

> [I]t is not for the Court to decide whether 'the plaintiff will actually or even probably prevail on the merits, but [rather to] look only for a possibility that he may do so.' In short, claims against a defendant must be 'patently spurious' or provide 'no reasonable basis for imposing liability' before that defendant can be disregarded for purposes of determining jurisdiction.

Mielke v. Conoco Phillips Co., Case 04-5502 (N.D. Cal. May 4, 2005)(Henderson, J.) (internal citations omitted). "In determining whether a defendant was joined fraudulently, the court must resolve 'all disputed questions of fact and all ambiguities in the controlling state law in favor of the non-removing party.'" *Plute*, 141 F. Supp.2d at 1008 (quoting *Dodson v. Spiliada Maritime Corp.*, 951 F.2d 40, 42-43 (5th Cir. 1992)). The courts strictly construe the removal statutes in favor of remand and against removal. *Duncan v. Stretzle*, 76 F.3d 1480, 1485 (9th Cir. 1996); *Brown v. Francis*, 75 F.3d 860, 864-65 (3rd Cir. 1996); *Diaz v. Shepard*, 85 F.3d 1502, 1505 (11th Cir. 1996); *Brinkley v. Univ. Health Serv., Inc.*, 194 F.Supp.2d 597 (S.D. Tex. 2002).

Finally, any doubts concerning the sufficiency of a cause of action due to inartful, ambiguous, or technically defective pleading must be resolved in favor of remand. *Plute* and *Dodson, Id.*

Merck must prove that there is no possibility that Plaintiffs would be able to establish a cause of action in state court against McKesson. In meeting this burden, Merck must overcome significant presumptions in Plaintiffs' favor. "To prove their allegation of fraudulent joinder [removing parties] must demonstrate that there is no possibility that [plaintiff] would be able to establish a cause of action against them in state court. In evaluating fraudulent joinder claims, we must initially resolve all disputed questions of fact and all ambiguities in the controlling state law in favor of the non-removing party. We are then to determine whether that party has any possibility of recovery against the party whose joinder is questioned." *Hart v. Bayer Corp*. 199 F.3d 239, 246 (5th Cir. 2000), (italic and brackets in original), quoted at length in *Montano v. Allstate Indemnity*, 211 F.3d 1278 (Table), 2000 WL 525592, *1 (10th Cir. 2000) (unpublished).

B. Plaintiffs Have Pleaded Sufficient Facts Against McKesson to State a Claim Under the California Strict Liability Law.

Merck argues that Plaintiffs failed to plead facts sufficient to state a cause of action against McKesson. Merck is wrong. Where, as here, a defendant challenges the factual sufficiency of a cause of action, the court must resolve all doubts in favor of the party seeking remand. *See Plute*, 141 F. Supp.2d at 1010, n.4. Indeed, the court must remand even when the complaint fails to attribute particularly any wrongful conduct to the in-state defendant. *Id.* (remanding case and stating "[u]nder the liberal pleading requirements, these general allegations are sufficient to charge [Defendants] with the alleged wrongful conduct"); *see also Peloza v. Capistrano Unified Sch. Dist.,* 37 F.3d 517, 521 (9th Cir.1994), *cert. denied,* 515 U.S. 1173, 115 S.Ct. 2640, 132 L.Ed.2d 878 (1995) (stating courts must interpret general allegations to "embrace whatever specific facts might be necessary to support them").

The general complaint is described above. Not only do the Plaintiffs specifically refer to McKesson, but make it clear, as described in note 3 above, that in referring to Merck's constructive knowledge of danger, the Plaintiffs included McKesson as well. The complaint sets out charges against both defendants for the marketing scheme.

Under California Strict Liability Law, a plaintiff must satisfy the following elements to prove a failure to warn claim: (1) that McKesson distributed Fosomax; (2) that Fosomax had potential risks or side effects that were known or knowable by the use of scientific knowledge available at the time of distribution; (3) that the potential risks or side effects presented a substantial danger to users; (4) that ordinary consumers would not have recognized the risks or side effects; (5) that McKesson failed to warn adequately of the risks or side effects; (6) that Fosomax was used in a way that was reasonably foreseeable to McKesson; (7) that Plaintiff was harmed; and (8) that lack of sufficient instructions or warnings was a substantial factor in causing Plaintiff's harm. *See* CACI Civil Jury Instruction 1205, containing these elements.[4] Plaintiffs have explicitly or implicitly pleaded each of these.

C. The California Learned Intermediary Doctrine Does Not Support Removal

Merck suggests that McKesson, as a distributor of drugs, does not have a duty to warn under California's "Learned Intermediary Doctrine." Again, Merck is wrong. Merck has not (and cannot) cite any California cases holding that a distributor cannot be held liable for failure to warn. Indeed, as set forth below, Merck's argument has already been rejected by at least four other courts in California and most recently, in a case involving similar facts. *See Sconiers, et al. v. Eli Merck & Co., et al.*, Slip Op. at p. 2 (C.D. Cal. March 29, 2006), Case 2:06-cv-01466-PA-

[4] The CACI Civil Jury Instructions, which contain the elements referenced above, are persuasive authority as to California law. *See* Rule 855 (a)&(e) of the California Rules of Court; *see also, In re Su,* 290 F.3d 1140, 1145-46, at n. 4 (9th Cir. 2002)(citing to CACI Instructions as persuasive of California Law); *See Crab Boat Owners Ass'n v. Hartford Ins. Co. of the Midwest*, 325 F.Supp.2d 1057, (N.D. Cal. 2004)(same).

PJW Document 10 Filed 03/29/2006. The general rule under California law is that both a manufacturer and a distributor can be strictly liable for injuries caused by a defective product. *Bostick v. Flex Equipment Co.*, 147 Cal.App.4th 80, 88, 54 Cal.Rptr.3d 28 (2007); *Anderson v. Owens-Corning Fiberglass Corp.*, 53 Cal.3d 987, 994, 281 Cal.Rptr. 528, 810 P.2d 549 (1991); see also *Daly v. General Motors Corp.*, 20 Cal.3d 725, 739, 144 Cal.Rptr. 380, 575 P.2d 1162 (1978); *Vandermark v. Ford Motor Co*., 61 Cal.2d 256, 262-63, 37 Cal.Rptr. 896, 391 P.2d 168 (1964). Accordingly, Merck cannot satisfy its heavy burden of proving that there is no possibility that Plaintiffs will prevail on the merits, and this case should be remanded.

California US District Courts have remanded cases to the state court, notwithstanding the defendant's invocation of the California Learned Intermediary Rule or that the California defendant was just a distributor. "The general rule is that strict liability for failure to provide adequate warnings runs to distributors as well as manufacturers." *Arderson v. Owens-Corning Fiberglas Corp.,* 53 Cal.3d 987, 994, 281 Cal.Rptr. 528, 810 P.2d 549 (1991). Such liability may also extend to retailers." *Martin v. Merck & Co., Inc.* 2005 WL 1984483, *3 (E.D.Cal.) (E.D.Cal.,2005); citing *Soule v. Gen. Motors Corp.,* 8 Cal.4th 548, 560, 34 Cal.Rptr.2d 607, 882 P.2d 298 (1994).

Martin next considers McKesson itself and asks whether a bar to liability for failure to warn for pharmacists might apply to it. But this argument necessarily fails. "First, California's public policy justification for exempting pharmacists from strict liability is that pharmacists provide services." *Martin, Id*. citing *Murphy v. E.R. Sguibb & Sons, Inc*., 13 Cal.4th 1104, 1117, 56 Cal.Rptr.2d 162, 920 P.2d 1347 (1996). ('a key factor' in exempting pharmacies from liability is 'that the pharmacist who fills a prescription is in a different position from the ordinary retailer because he cannot offer a prescription for sale except by order of the doctor.... He is providing a

service to the doctor.')." But, *Martin* continues, "McKesson, unlike pharmacists, does not provide the public with an analogous service." *Martin* at *4. Indeed, it provides a service **to Merck**. More importantly however, by relying primarily on public policy arguments, Merck effectively conceded that such a cause of action is not presently precluded under California law. Therefore, Merck failed to meet its heavy burden to show to "a near certainty" that McKesson's joinder was fraudulent in that case.

Other California Courts have reached the same result. See *Maher v. Novartis Pharmaceuticals Corp.*, NO. 07CV852 WQH (JMA), 2007 WL 2330713, *3 (S.D.Cal.) (S.D.Cal. 2007); *Sokarda v. Merck*, Slip Op., Case 8:05-cv-00177-JFW-MAN Document 29 Filed 04/22/2005 (C.D. Cal., April 25, 2005) (also granting remand where McKesson was joined as defendant); and *see Sconiers,* above.[5]

D. Federal Preemption Does Not Support Removal

Merck also argues that McKesson was fraudulently joined on a warnings claim because the FDA approved Merck's warnings on Fosamax.

As a general matter, Merck cannot use its affirmative defense of federal preemption as a basis for removal. "[A] case may *not* be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." *See Caterpillar, Inc. v. Williams,* 482 U.S. 386, 392 (1987); *see also Ritchey,* 139 F.3d at 1319 (stating "[e]ven when the area involved is one where complete preemption is the norm, if

[5] Some recent Merck cases involving McKesson have denied remand, but without prejudice, to allow the MDL Court to decide. *See, e.g.*, *Bernstine v. Merck & Co., Inc.*, (NO. S-07-0034 WBS KJM, S-07-0051 WBS KJM, S-07-0073 WBS KJM), 2007 WL 1217589 (E.D.Cal. Apr 24, 2007) (remand denied *without prejudice* to refilling to allow the MDL Panel or Court to resolve the issue); *Hardin v. Merck & Co., Inc.*, (NO. C 07 0070 SBA), 2007 WL 1056790 (N.D.Cal. Apr 05, 2007) (again, "prejudice to being reurged before the MDL court.").

the complaint relies on claims outside of the preempted area and does not present a federal claim on its face, the defendant must raise its preemption defense in state court").

In addition, courts have overwhelmingly rejected the notion that state law failure to warn claims are preempted by federal law. *See, e.g., Medtronic, Inc. v. Lohr,* 518 U.S. 470, 497-502 (1996) (plur. opn. of Stevens, J.) (holding negligence and strict liability claims based on failure to warn theory not preempted by federal regulations); *Brannan v. United Student Aid Funds, Inc.,* 94 F.3d 1260, 1265 (9th Cir. 1996) (citing *Medtronic* with approval); *Carlin v. Superior Court*, 13 Cal.4th 1104, 1113 (1996) (denying FDA preemption of California failure to warn claims because state law failure to warn claims not inconsistent with federal policy); *Motus v. Pfizer, Inc.,* 127 F.Supp.2d 1085, 1091-1101 (C.D. Cal. 2000) (denying FDA preemption because federal regulations do not bar claims for strict liability under state law).[6] Based on the foregoing Merck cannot demonstrate that Plaintiffs will be unable to prevail on their claims against McKesson based on the affirmative defense of federal preemption. Accordingly, Plaintiffs' motion to remand should be granted.

E. The Court Should Award Costs and Attorney Fees Pursuant to 28 U.S.C. § 1777(c).

Finally, Plaintiffs respectfully request that this Court award the costs and attorney fees that they have incurred in seeking remand in this case. A district court "may require payment of just costs and any actual expenses, including attorney fees, incurred as a result of removal." 28 U.S.C. 1777(c). As described above, the Defendant's notice of removal is patently improper and fails on its face to establish any basis for federal jurisdiction. In addition, as noted above, Merck

[6] Merck's reliance on *Brown v. Superior Court,* 44 Cal. 3d 1049, 1069, n.12, 751 P.2d 470, 245 Cal.Rptr. 412 (1988) is both mysterious and misplaced. It is mysterious because nothing contained in the opinion as a whole, discusses any of the preemption issues relevant here. In that case there was no complaint at all directed against the fraudulently joined defendant. Further, as discussed above, it is misplaced because in *Carlin*, 13 Cal.4th at 1113-15, the California Supreme Court expressly rejected the notion that federal law preempts strict liability failure to warn cases.

has attempted to remove this case, notwithstanding the fact that the district has already resolved this issue in favor of state jurisdiction. This tends to demonstrate Merck's bad faith in seeking removal in this case. Accordingly, the Court should award Plaintiffs reasonable and necessary costs and attorneys fees in accordance with 28 U.S.C. § 1777(c).

III.
CONCLUSION

As demonstrated above, Merck cannot meet its heavy burden of proving there is no possibility of Plaintiffs establishing a cause of action against McKesson in a California state court. Accordingly, Plaintiffs respectfully request that this Court remand this case to state court. Plaintiffs further request the Court grant Plaintiffs all other relief in law or equity as the Court deems just and right.

DATED: October 31, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing *Memorandum in Support of Motion to Remand* was served in accordance with Case Management Order No. 3 and this Court's Procedures for Electronic Case Filing, , this 31st day of October, 2007.

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